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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,762	12/28/2000	Kazuyuki Yanase	114474-14-FESI00002US	5214
38492 7590 11/23/2010 WILLKIE FARR & GALLAGHER LLP INTELLECTUAL PROPERTY LEGAL ASSISTANTS 787 SEVENTH AVE NEW YORK, NY 10019-6099				
EXAMINER				
HAMO, PATRICK				
ART UNIT		PAPER NUMBER		
3746				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

09/720,762

**Applicant(s)**

YANASE ET AL.

**Examiner**

PATRICK HAMO

**Art Unit**

3746

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6-9, 11, 13, 19-22, 33-37, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-9, 11, 13, 19-22, 33-37, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to amendments filed on September 7, 2010.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6-9 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trull et al., 6,080,136 in view of Ivey, 5,976,299 further in view of Sudo et al., 5,009,646, and further in view of Akaike et al., 5,061,247.

Trull, in figure 6, discloses a syringe gasket (70) wherein a peripheral side surface (80) of the gasket is in contact with an inner surface of the syringe barrel (60). A restriction and a tapered slant with a first and second plunger diameter (see fig. 6) is provided, and a periphery of a bottom surface of the gasket that is not in contact with the liquid is formed into a tapered slant (see fig. 6).

Trull does not teach that the barrel is composed of a polyethylene fiber or one or both of the peripheral side surfaces that is in contact with an inner surface of the syringe barrel and a surface of the gasket that is in contact with the liquid is laminated with polyethylene fluoride resin.

However, Ivey teaches the use polyethylene film, composed of polyethylene fibers (col. 5, lines 1-4) to make sterilizable receptacles for medical use, including syringes (col. 1, lines 13-24). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to have made the barrel of Trull out of polyolefin fibers to make the syringe sterilizable and therefore reusable.

Furthermore, Sudo teaches a syringe gasket (2) coated (3) with a thermoplastic resin such as polyethylene (col. 2 lines 10-24) to provide sealing and lubrication while preventing contamination from liquid lubricants (col. 1 lines 48-55). In regard to the claimed limitation that the restriction has an inner diameter ratio of 0.93 or more and less than 1.0 of a diameter of the gasket, this constitutes a change in proportion of the gap 6 taught by Sudo. In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. It would have been obvious to one of ordinary skill in the art to try the claimed ratio.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Trull et al. gasket by using a gasket material of polyethylene, as taught by Sudo et al., in order to eliminate the need for a lubricant and serve as a protective sealant coating for the gasket.

With respect to the fact that Sudo teaches the coating for more than just the peripheral side surface, namely the top surface in contact with the pumped liquid as a sealant, it is brought to applicant's attention that the bottom surface is not coated. This surface is not coated because coating it with a lubricant or sealant is not required. The coating has two functions, namely to lubricate and to seal. For the side surface, both of these functions are utilized. For the top portion, only the function of sealant is being utilized. In the present application, the coating and its function (sealing) are removed from the top surface. This does not add patentable weight because it would have been obvious to omit the coating where the function attributed to the coating is not desired or required. See MPEP §2144.04(2)(a).

Furthermore, Trull does not teach that the first and second diameter of the tapered slant have a difference between about .5mm and about 5mm or that the gasket's inner diameter, its height, its first diameter, or its second diameter. With respect to the specified gasket dimensions in the claims 3, 6-8, 19, 21,22, and 24-28, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136.

With respect to claim 9, a second tapered (see examiner's marked up Figure 6 in the office action dated October 2, 2006) slant is formed between the peripheral side surface of the gasket (70) that is in contact with an inner surface of the syringe barrel

(60) and the restriction (see examiner's marked up Figure 6). The gasket tightly closing the liquid is an obvious requirement for the syringe to pump fluid properly. A recitation with respect to the material intended to be worked upon by a claimed apparatus, in this case a contrast medium, does not impose any structural limitations upon the claimed apparatus, which differentiates it from the prior art apparatus satisfying the structural limitations of the claims, as is the case here.

The above teach all of the limitations substantially as claimed except for the following: the gasket being made integrally of a material with JIS hardness of 55 to 60.

However, Akaike et al., in column 5 lines 58-59, disclose, that a hardness of JIS of 20-85 is optimal for gaskets applied to syringe devices. This general range covers the applicants claimed range. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify references as applied to claims 1 and 9 above with a gasket material of 20-85 JIS hardness in order to achieve optimum gasket functionality within a syringe device. With respect to the specific range of JIS hardness 55 to 60, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Swain et al., 33 CCPA (Patents) 1250, 156 F.2d 239, 70 USPQ 412; Minnesota Mining and Mfg. Co. v. Coe, 69 App. D.C. 217, 99 F.2d 986, 38 USPQ 213; Allen et al. v. Coe, 77 App. D.C. 324, 135 F.2d 11, 57 USPQ 136. It would have been obvious to one of ordinary skill in the art to try the claimed hardness as it is fully within the range discussed in the prior art.

Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1 and 9 above, and further in view of Higashikawa, 5,830,193.

The references as applied to claim 1 above teach all of the limitations substantially as claimed except for the following: that the syringe includes a luer lock.

However, Higashikawa in Figure 1a-1c, 7a, and 7b, teaches that luer lock mechanisms (37, 30, 22) have been especially common in medical syringes (21) for mounting needles (32) - see column 7 line 49.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the references as applied to claims 1 and 9 above by incorporating the luer locking mechanism, as taught by Higashikawa, in order to allow for needle mounting.

Claims 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 1 in view of Vacca, 5,531,255.

The references as applied to claim 1 above teach all of the limitations substantially as claimed except for the following: that only wherein the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with silicon.

However, Vacca teaches that adding lubricant to a syringe improves its performance and that silicon is a suitable lubricant (col. 3, ll. 14-18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the references if claim 1 above with the silicon lubrication of Vacca in order to improve the performance of the syringe.

### ***Response to Arguments***

Applicant's arguments, see p. 7, filed September 7, 2010, with respect to the rejections under 35 USC 112 have been fully considered and are persuasive. The rejection under 35 USC 112 has been withdrawn.

Applicant's arguments filed September 7, 2010 with respect to rejections under 35 USC 103 have been fully considered but they are not persuasive.

With respect to applicant's affidavit submitted in support of the claimed JIS hardness of 55-60, the examiner first notes that the affidavit is in support of a JIS hardness of either 57-59 or 57-60, not the more broadly claimed 55-60. Furthermore, it does not overcome the *KSR* standard of "obvious to try" given that Akaike discloses a JIS hardness range of 20-85, including completely the range claimed by the applicant. It remains obvious for a person of ordinary skill in the art to experiment with hardness within Akaike's disclosed range to determine an optimum operating hardness. Therefore, examiner respectfully reasserts the rejection above.

The examiner also respectfully disagrees with applicant's contention that Sudo teaches away from the claimed limitation and therefore cannot read on the claims. Firstly, the examiner does not contend that Sudo's gap has the same dimensions as the claimed restriction. In fact, the examiner does not imply that Sudo even contemplates



specific dimensions for the depth or width of the gap. However, it remains that Sudo teaches a gap with a width undisclosed that corresponds to the claimed restriction. Furthermore, the examiner, in the prior action and above, acknowledges that Sudo teaches laminating more than the portion of the syringe claimed. However, as stated above and previously, it would have been obvious to omit the lamination of a portion of the syringe *and* its function. To repeat, with respect to the fact that Sudo teaches the coating for more than just the peripheral side surface, namely the top surface in contact with the pumped liquid as a sealant, it is brought to applicant's attention that the bottom surface is not coated. This surface is not coated because coating it with a lubricant or sealant is not required. The coating has two functions, namely to lubricate and to seal. For the side surface, both of these functions are utilized. For the top portion, only the function of sealant is being utilized. In the present application, the coating and its function (sealing) are removed from the top surface. This does not add patentable weight because it would have been obvious to omit the coating where the function attributed to the coating is not desired or required. See MPEP §2144.04(2)(a). The examiner respectfully submits that the reference was considered as a whole, including the portions that applicant argues lead away from the claimed invention.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Hitchins et al., US 6,017,330 teaches a plunger with JIS hardness from 50-60.

Higashikawa, US 5,830,193 teaches a syringe with a gasket including restrictions and a polyolefin barrel.

Shaw et al., US 3,121,040 teaches polyolefin filaments including annular filaments.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICK HAMO whose telephone number is (571)272-3492. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Devon Kramer can be reached on 571-272-7118. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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